

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventors : Craig S. Aman
Application No. : 09/739,357
Filed : December 19, 2000
For : WEB ENABLED MEDICAL DEVICE TRAINING

APPEAL BRIEF

On Appeal from Group Art Unit 3714

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands, successor by assignment from the original assignee, Agilent Technologies.

II. RELATED APPEALS AND INTERFERENCES

A first appeal in this case was filed August 3, 2005 and was briefed by applicant. This appeal was terminated when prosecution of the case was reopened by the Office action mailed June 6, 2006. There are no related interferences.

III. STATUS OF CLAIMS

Claims 1-25 and 38-47 are pending in the application and stand finally rejected. Claims 26-37 and 48-49 have been canceled. The claims being appealed are Claims 38-43.

IV. STATUS OF AMENDMENTS

No amendment was filed in response to the final Office action mailed July 13, 2007.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per Claim 38 and its dependent claims is a method for providing instruction on the use of a medical device to a user computer. The inventive method may be carried out by a server computer 102 which communicates over a network 104 to a trainee computer 106 (Claims 38 preamble:

"user computer") as shown in Fig. 1 and described on page 5, lines 13-25. The method begins in the illustrated example with a request for instruction on use of a medical device from the trainee computer 106 running a medical device training program 202 as described at column 7, lines 18-25. In the illustrated example the medical device is an automated external defibrillator. The request causes a series of operational steps to be performed by the server 102. The server responds by providing a list 502 of instructional topics associated with the defibrillator. This list is displayed on the graphical user interface of the trainee computer 106 as shown by the training topic screen in the constructed embodiment of Fig. 5 and discussed on page 9, lines 13-21. As explained in this passage, selecting an item on the list 502 will cause a related list 602 of instructional subtopics to appear on the graphical user interface. Such a subtopic screen display 600 is shown in Fig. 6 and is easily accessed in this embodiment because topics on the first list are constructed as links. The subtopic screen display 600 is described on page 8, line 23 through page 9, line 9. When the trainee user selects one of the instructional subtopics 602 a plurality of instructional graphical user interface screens 700-1100 pertaining to the subtopic are presented. These screens provide simulated hands-on operation of the defibrillator by providing a medical device control object simulating a control of the defibrillator (Claim 38, element a)) and a medical device first aid object (Claim 38, element b)) of the defibrillator. For instance, Fig. 8 displays medical device first aid instrument objects of the defibrillator, simulated electrode pads 820, which the trainee user is asked to place on the chest of the simulated patient. The user selects the pads 820 on the screen and manipulates them (Claim 38, element g)) to place and position the pads in the proper locations on the patient's chest as described on page 9, lines 25-29. The

trainee user can also click on the "AUDIO" icon to hear the actual audio instructions played by the defibrillator during its use as described on page 10, lines 14-15 and page 10, line 24 through page 11, line 13. The user can observe a live video of the ECG trace as shown in Fig. 9 and, if a shock is advised, can press a medical device control object of the defibrillator, the simulated orange shock button 1024, as shown in Fig. 10. For each simulation, interaction feedback is provided (Claim 38, element c)) to assess the trainee user's competence in operating the defibrillator controls and manipulating the simulated electrode pads to correctly place them on the simulated patient as shown in Fig. 9. The feedback indicates to a trainee user whether a simulation interaction is appropriate, as well as the correctness of the user interaction with the medical device control object and the medical device first aid instrument object (Claim 38, element c)) as described on page 8, lines 4-13. The tutorial is accompanied by context-related text, images and videos illustrating use of the medical device and first aid object with patients as shown in Fig. 7 and Fig. 10 at 710 and 714 and described on page 10.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claims 39-40 stand correctly rejected under 35 U.S.C. §102(e) as anticipated by U.S. Pat. 6,537,714 (Melker et al.) and whether Claims 38 and 41-43 stand correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Melker et al. in view U.S. Pat. 5,791,907 (Ramshaw et al.).

VII. ARGUMENT

A. Rejection of Claim 38 as unpatentable over Melker et al. and Ramshaw et al.

Claim 38 is the only independent claim on appeal. Claim 38 describes a method for providing instruction on the use of a medical device to a user computer, the method comprising a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device; b) providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device; g) allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object. An embodiment of this invention provides two types of training for a medical device: both its operation and its use with a patient. In the case of a defibrillator, for example, the first aid instrument object would be the electrode pads and the control object would be the defibrillator controls. The instruction method would teach the student on the proper operation of the defibrillator controls and on correct placement of the electrode pads on the patient, for instance. Correct placement of electrode pads is essential for a successful defibrillation. If the student would attempt to analyze the ECG or measure patient

impedance before attaching the pads to the patient, for instance, the instructional program would alert the student that the intended analysis or measurement was incorrect because the electrode pads have to be attached to the patient before either analyzing the ECG or measuring patient impedance.

Melker et al. describes a training computer called a "PTT" which may be embodied as a handheld "tablet" computer. The PTT provides training by instructional modules and interactive modules. The interactive module displays the controls of a medical device on the PTT and also the output of the device such as a display. See column 6, lines 3-19 of Melker et al. Alternatively, the PTT connects to an actual medical device via an RS-232 port and receives input signals from actuation of the controls of the device. See column 6, lines 20-27 of Melker et al. In either case the PTT tracks the operation of the controls to gauge the student's ability to operate the device. See column 3, line 35 and column 7, lines 50-63 of Melker et al. Thus, the PTT measures the student's skill by his or her ability to operate the controls of the actual or simulated medical device. There is no suggestion of training by having a student manipulate both medical device control objects and medical device first aid instrument objects as called for by Claim 38. The Examiner's rejection admits as much at the bottom of page 5 of the Office action of July 13, 2007.

To make up for this deficiency, the Examiner cites Ramshaw et al., which is a computerized training system for surgical procedures. As shown in Figs. 5-11 of Ramshaw et al., this surgical training system asks the student to identify instruments which are to be used for various steps of the surgical procedure. In Figs. 5A and 5B, the student is expected to identify a hemostat to be used for the next step of the procedure. When the student correctly identifies the next instrument, the system plays

a video showing the use of the instrument in the next step as shown in Figs. 7-8. The student is not expected to manipulate a simulated or actual instrument, only to select it. And there are no device controls to manipulate, only instrument selection. Thus, it is respectfully submitted that Ramshaw et al. fails to supply the elements missing from Melker et al. that are needed to render Claim 38 unpatentable. An embodiment of the present invention will provide a fully, more complete, and more realistic training scenario of a medical device and first aid object than is possible with any combination of Melker et al. and Ramshaw et al.

B. Rejection of dependent Claims 39-43

Claims 39-43 all ultimately depend from Claim 38. Since Claim 38 has been shown to be patentable over the combination of Melker et al. and Ramshaw et al., it is respectfully submitted that Claims 39-43 are patentable over these patents by reason of their dependency.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 38-43 are patentable over the combination of the Melker et al. and Ramshaw et al. patents. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection stated in the July 13, 2007 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 38-43 are the claims involved in the appeal.

- 38) (Previously presented) A method for providing instruction on the use of a medical device to a user computer, the method comprising:
 - a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device;
 - b) providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device;
 - g) allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and
 - c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object.
- 39) (Original) The method according to claim 38, wherein the medical device is an Automatic External Defibrillator (AED).
- 40) (Original) The method according to claim 38, further comprising:
 - d) providing an audio, the audio disclosing instructional information related to the medical device.
- 41) (Previously presented) The method according to claim 38, further comprising:
 - d) providing text description of one or more operational steps pertaining to the medical device.

- 42) (Previously presented) The method according to claim 41, further comprising:
- e) providing one or more still images illustrating the concept disclosed by the text description of the one or more operational steps.
- 43) (Previously presented) The method according to claim 41, further comprising:
- e) providing a video illustrating the concept disclosed by the text description of the one or more operational steps.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted by either party in this case.

APPENDIX C: RELATED PROCEEDINGS

None. There are no related proceedings.